10/781,254

EXHIBIT A

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit:	1617
Confirmation No:	3157
Application No.:	10/781,254
Filing Date:	February 18, 2004
Inventor:	Joel E. Bernstein
Title:	COMPOSITIONS AND METHOD FOR TREATING AFFECTIVE, PAINFUL OR ALLERGIC DISORDERS
Attorney Docket No.:	41959-102742
Examiner Name:	Kim, Jennifer M.

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. I, Joel E. Bernstein, am the sole inventor of U.S. Application No. 10/781,254 (the "Application").

2. I am the Chief Executive Officer of Winston Laboratories, Inc.

3. I reside at 615 Brierhill Road, Deerfield, IL 60015.

4. As agreed upon during an interview conducted with examiner Jennifer Kim on January 9, 2008, I am submitting this Declaration in support of pending independent claims 1 and 11 of the Application which states that compositions containing "a preponderance of cis doxepin isomer over trans doxepin isomer" are "comparable in efficacy to compositions containing a preponderance of the trans doxepin isomer but with significantly less sedative effects."

5. In support of pending independent claims 1 and 11, I am herein submitting the following comparative investigative data:

(a) In a study utilizing twenty-eight (28) young adult rats, rats receiving single oral dosages of cis doxepin (90% cis doxepin/10% trans doxepin) up to 300 mg/kg, and observed for an additional 14 days, demonstrated virtually no sedation versus rats receiving between 100-150 mg/kg of doxepin USP (85% trans doxepin/15% cis doxepin) who all demonstrated severe sedation.

(b) Five (5) adult patients suffering from either painful fibromyalgia, (3 patients) or chronic urticaria, (2 patients) received a 10 mg capsule containing doxepin USP (85% trans doxepin/15% cis doxepin) twice daily for two weeks, and then, after a one week wash-out period, received a capsule twice daily for two weeks containing 10 mg of a composition in which cis doxepin constituted 90% of the active agent and the trans isomer 10%. The patients observed that they obtained equal relief from the two formulations for the pain of fibromyalgia or the pruritus of chronic urticaria. However, all five reported moderate (2 patients) to severe (3 patients) sedation with the doxepin USP capsules versus only one of the five patients experiencing moderate sedation with the capsules containing predominantly the cis doxepin isomer and the other 4 patients experiencing no sedation.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the Untied States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully Submitted,

Date: Feb. 13, 2008

By: _____

Joel E. Bernstein M.D.